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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/603,409	06/26/2000	Dirk V. Hoyns	B0762/7001	3130

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EXAMINER

HO, UYEN T

ART UNIT	PAPER NUMBER
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3731

DATE MAILED: 07/17/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/603,409	Applicant(s) HOYNS, DIRK V.	
	Examiner (Jackie) Tan-Uy n T. Ho	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 June 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 6, 14, 15, 24, 25, 30-34 and 40-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 7-13, 16-23, 26-29 and 35-39 is/are rejected.
- 7) ☒ Claim(s) 4 and 5 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>4</u> . | 6) <input checked="" type="checkbox"/> Other: <i>Attachment I</i> . |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-39, drawn to a stent, classified in class 623, subclass 1.15.
 - II. Claims 40-43, drawn to a method of making a stent, classified in class 623, subclass 1.15.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as apparatus and product made. The inventions in this relationship are distinct if either or both of the following can be shown: (1) that the apparatus as claimed is not an obvious apparatus for making the product and the apparatus can be used for making a different product or (2) that the product as claimed can be made by another and materially different apparatus (MPEP § 806.05(g)). In this case the product as claimed can be made by another and materially different apparatus.
3. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
4. This application contains claims directed to the following patentably distinct species of the claimed invention: Species I: Figs. 1-7; Species II: Figs. 10-11; Species III: Figs. 12-18.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, there is not any generic claim.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

5. During a telephone conversation with Mr. Arthur Bookstein on 7/11/2002 a provisional election was made with traverse to prosecute the invention of invention I, Species I, claims 1-5, 7-13, 16-23, 26-29 and 35-39. Affirmation of this election must be made by applicant in replying to this Office action. Claims 6, 14-15, 24-25, 30-34 of Invention I and 40-43 of Invention II have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

7. Claim 38 is objected to because of the following informalities: In line 2, "6" should be "six". Appropriate correction is required.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claim 29 recites the limitation "the paralleling relations" in line 1. There is insufficient antecedent basis for this limitation in the claim.

10. Claim 8 recites the limitation "the gap " in line 1. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

12. Claims 1-3, 7-13, 16-18, 20-23, 26-29 and 35-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Ehr et al. (6,334,870).

Ehr et al. disclose a stent including: (See attachment I)

In regard to claims 1 and 23:

- A plurality of nodes
- A central hub for each node
- At least three arms extending from the hub
- A transition region where each arm being connected to an arm of an adjacent node
- A link between the nodes being defined by the connected arms of the adjacent nodes

In regard to claims 2 and 3:

- The arms in the links of adjacent nodes curve in opposite directions
- The links are S-shaped

In regard to claim 7:

- The arms of the nodes are arranged generally to define a spiral

In regard to claims 8-10:

- A gap between adjacent arms of a spiral is of substantially constant width up to the transition region
- Each of the arms of a node is connected at a root to the hub of the node
- Each arms of each node is connected to a different one of the adjacent nodes

In regard to claims 11-13:

- A plurality of adjacent pairs of nodes lie along radially extending planes and the planes being spaced along the length of the stent
- The links between nodes of the pairs lie along the radial planes and extend in a circumferential direction
- Additional pairs of adjacent nodes extending along a row that extends generally helically along the stent

In regard to claims 16-18 and 20-22:

- The transition region is disposed at the mid-portion of the link
- The stent is formed from stainless steel
- The stent having a low profile and expanded diameters adapted to be deployed within a human biliary duct, blood vessel, urological passage (inherent)

In regard to claims 26-29 and 37:

- The nodes are arranged in clusters of six nodes each

- The arms of the nodes are arranged generally to define a spiral
- The nodes arranged in a plurality of helical row, the nodes in each row being serially connected to each other by a link

In regard to claims 35 and 36:

- A plurality of nodes
- S-shaped links connecting adjacent nodes
- A central hub for each node
- Three arms extending from the hub

In regard to claims 38 and 39:

- The nodes being arranged in clusters of six in which two arms of each node are connected to nodes of a cluster and one arm of each of the nodes in that cluster is connected to a node of another cluster.
- Each of the nodes in the stent is shared by three adjacent clusters

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ehr et al. (6,334,870). Ehr et al. disclose all the limitations of the claims (as described above) except for a metal having shape memory characteristics adapted to enable the stent to

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expand in response to a thermal event being used to form the stent. It would have been obvious matter of design choice to make the stent of Ehr et al. from a metal having shape memory characteristics as claimed, since applicant has not disclosed that having the stent made from the claimed material solves any stated problem or is for any particular purpose and it appears that the stent would perform equally well in either materials, stainless steel or a metal having thermal shape memory.

Allowable Subject Matter

15. Claims 4 and 5 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. The following is a statement of reasons for the indication of allowable subject matter: The prior art fails to disclose or suggest a stent including a plurality of nodes arranged in a hexagonal cluster, each node having a central hub and three arms extending from the hub, each arm circumscribing the hub and each arm being connected, at a transition region, to an arm of an adjacent node.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Ley et al. (6,395,020) and Ley (6,231,599) disclose a stent including nodes, links, hub, arms.

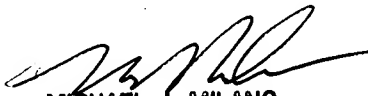
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17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to (Jackie) Tan-Uyen T. Ho whose telephone number is (703) 306-3421. The examiner can normally be reached on MULTIFLEX Mon. to Sat..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael J. Milano can be reached on (703) 308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3590 for regular communications and (703) 305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

(Jackie) Tan-Uyen T. Ho
July 15, 2002


MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

